PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kathryn Sykes, Katherine Hale
And Stephen Johnston

Serial No.: 10/688,058

Filed: October 17, 2003

For: METHODS AND COMPOSITIONS FOR VACCINATION COMPRISING NUCLEIC ACID AND/OR POLYPEPTIDE SEQUENCE OF THE GENUS BORRELIA

Group Art Unit: 1645

Examiner: Rodney Swartz

Atty. Dkt. No.: UTSD:872US

Confirmation No.:9509

CERTIFICATE OF ELECTRONIC TRANSMISSION
37 C.F.R. § 1.8

I hereby certify that this Supplemental Appeal Brief is being electronically filed with the United States Patent and Trademark Office via EFS-Web on the date below:

June 29, 2007
Date

Travis M. Wohlers

SUPPLEMENTAL APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Notification of Non-Compliant Appeal Brief (37 CFR 41.37) dated June 1, 2007. The deadline for filing a response is July 1, 2007.

No fees are believed due at this time, however, should any fees be required under 37 C.F.R. §§ 1.16 to 1.21, please consider this paragraph such a request and authorization to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTSD:872US.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Board of Regents, The University of Texas System.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 40-43, 48, and 88-91 are pending in the application, with claims 1-39, 44-47, and 49-87 having been previously canceled. Claims 40-43 have been withdrawn from consideration. Claims 48 and 88-91 stand rejected. Appellant appeals the rejection of claims 48 and 88-91. A copy of claims 48 and 88-91 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments are pending.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 48 is directed to A vaccine composition comprising a pharmaceutically acceptable carrier and at least a first Borrelia antigen or a first polynucleotide encoding the first Borrelia antigen, wherein the first Borrelia antigen comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID

NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID NO:102, SEQ ID NO:104, SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139 or fragments thereof; and wherein the vaccine composition does not contain a whole-cell lysate of a Borrelia pathogen. Support for claim 48 may be found in the specification at page 9, lines 13-25; page 12, line 15 to page 13, line 23; and page 14, line 22-28.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 48 and 88-91 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Choi *et al.* (WO 98/59071).

Claims 48 and 88-91 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

VII. ARGUMENT

A. *Substantial Evidence is Required to Uphold the Examiner's Position*

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312.

Accordingly, it necessarily follows that an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

B. *The Rejection of Claims 48 and 88-91 under 35 U.S.C. § 102(b) as being anticipated by Choi* et al. *(WO 98/59071)*

The Action rejects claim 31, 32, 34, and 44-51 under 35 U.S.C. § 102(b) as being anticipated by Choi et al. (WO 98/59071). Appellant traverses this rejection.

A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. Mere naming or description of the subject matter is insufficient if it cannot be produced without undue experimentation. MPEP § 2121.01; *see also Elan Pharms, Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221, 1228 (Fed. Cir. 2002) (stating "The anticipating reference 'must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.'").

Choi appears to describe a *B. burgdorferi* sequencing project. While Choi discloses hundreds of sequences reportedly obtained from *B. burgdorferi* (see Table 1 on pages 56 to 215), it fails to disclose a single example where even one of these sequences was used to elicit an immune response in an animal. Choi has done nothing more than venture a guess that one or more of the hundreds of *B. Burgdorferi* genes or gene fragments that were sequenced and listed in the specification would be useful antigens in a vaccine (Choi, p. 37, ln. 5, to p. 38, ln. 19). In order to obtain Appellant's claimed vaccine composition from Choi, a person of ordinary skill in the art would have to analyze an enormous number of *Borrellia* sequences. This is analogous to

a "needle-in-the-haystack" approach. Courts have found no anticipation from these types of disclosures. *See Ex parte Garvey*, 41 U.S.P.Q. 583 (Pat & Trademark Office Bd. App. 1939). The disclosure by Choi would not enable one skilled in the art to make and use a vaccine composition comprising a *Borrellia* antigen without undue experimentation, particularly in view of the known unpredictability in developing *Borrellia* vaccines and the lack of any working examples in Choi.

As described in the background of the present specification, there have been difficulties associated with immunization against *Borrelia*. For example, antibodies against a number of *B. burgdorferi* antigens have been found to cross-react with host nerve cell axons, synovial cells, hepatocytes, and cardiac muscle proteins, making whole-cell vaccines or vaccines with certain cross-reactive antigens undesirable (Specification, p. 7, ln. 12-14). The concern of vaccine-induced autoimmunity has focused the development of a vaccine for human Lyme disease on a subunit rather than whole-cell design (Specification, p. 7, ln. 16-18). However, only one FDA licensed vaccine against *Borrelia* (LYMErix), which is comprised of recombinant OspA, has been developed (Specification, p. 7, ln. 24). LYMErix was eventually pulled from the market (Specification, p. 8, ln. 30 to p. 9, ln. 2).

In contrast to the lack of guidance in the Choi disclosure as to which *Borrellia* sequences may be effective antigens in a vaccine, Appellant's specification demonstrated that vaccinating mice with the *Borrellia* antigens encompassed by the current claims provided protection from challenge with subcutaneously injected *B. burgdorferi* spirochetes as assayed by tibiotarsel joint diameter measurements and spirochete densities (see e.g., p. 88, ln. 15-29). Specifically, the SEQ ID NOs recited in current claim 48 are also identified in Table 2 of the specification (p. 89-94) as corresponding to the fragments and full-length coding regions of 34 clones identified in

the second round of array analysis at the intersections of positive groups based on inflammation data or spirochete density data (p. 89, ln. 12-18).

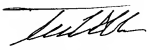
The disclosure in Choi is insufficient to enable the presently claimed vaccine, particularly given the art-recognized challenges associated with identifying *Borrelia* antigens that are effective at eliciting an immune response and do not induce an autoimmune reaction in the host. A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. Appellant, therefore, requests that the Board overturn this rejection.

C. *The Rejection of Claims 48 and 88-91 Under 35 U.S.C. § 112, Second Paragraph*

The Examiner rejected claims 48 and 88-91 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the examiner alleges that claim 48 is indefinite because it was amended such that it is drawn to a non-elected invention. Appellant traverses this rejection.

The amendment to claim 48 merely involved re-writing the claim in independent form by incorporating the language of claims 31 and 44 from which claim 48 previously depended. Claims 31, 44, and 48 were all included in the Group II invention according to the Restriction Requirement dated June 24, 2005. Accordingly, the present rejection is improper. Appellant, therefore, requests that the Board overturn this rejection.

Respectfully submitted,



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VIII. APPENDIX A – APPEAL CLAIMS

48. A vaccine composition comprising a pharmaceutically acceptable carrier and at least a first Borrelia antigen or a first polynucleotide encoding the first Borrelia antigen, wherein the first Borrelia antigen comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID NO:102, SEQ ID NO:104, SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139 or fragments thereof; and wherein the vaccine composition does not contain a whole-cell lysate of a Borrelia pathogen.

88. The vaccine composition of claim 48 comprising at least a second Borrelia antigen that is different from the first Borrelia antigen and comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID NO:102, SEQ ID NO:104,

SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139, or fragments thereof.

89. The vaccine composition of claim 88 comprising at least a third Borrelia antigen that is different from the first and the second Borrelia antigens and comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID NO:102, SEQ ID NO:104, SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139, or fragments thereof.

90. The vaccine composition of claim 89 comprising at least a fourth Borrelia antigen that is different from the first, the second, and the third Borrelia antigens and comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID

NO:102, SEQ ID NO:104, SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139, or fragments thereof.

91. The vaccine composition of claim 48, wherein the first Borrelia antigen comprises an amino acid sequence of SEQ ID NO:8 or a fragment thereof.

IX. APPENDIX B - EVIDENCE APPENDIX

None

X. APPENDIX C - RELATED PROCEEDINGS

None